REMARKS

Claims 25-35, 37-43, 46-47, 50, 52-62, 64-71, 73, 75-76, 79, and 81-100 are pending herein. By this Amendment, Claims 36 and 63 and non-elected Claims 44-45, 48-49, 51, 72, 74, 77-78, and 80 are canceled, without prejudice or disclaimer; Claims 25, 35, 39, 43, 46, 52, 62, 71, 75, 79, 81, 83, 86, and 89 are amended; and new Claims 91-100 are added. Support for the claim amendments and new claims is found in the specification at, *inter alia*, page 10, lines 10-15, page 11, lines 13-19, page 13, lines 26-31, page 23, lines 20-23, and page 26, lines 17-20. No new matter is added by this Amendment.

I. RESTRICTION REQUIREMENT

Further to a Restriction Requirement dated September 9, 2002, Applicants elected Group I (Claims 25-43, 46-47, 50, 52-71, 73, 75-76, 79, and 81-90) without traverse. As to the Election of Species dated February 26, 2002, Applicants elected a probiotic nutraceutical component, a durum wheat plasticized matrix, and a fat hydrophobic component.

The Examiner has not provided any statement in the current Office Action as to why elected Claims 26, 41, 43, 47, 50, 53, 68, 71, 79, and 81-90 are withdrawn from consideration. Each of these claims is directed to an elected encapsulated product. Even if these claims do not recite the elected species of a probiotic nutraceutical component and a durum wheat plasticized matrix (the election of species requirement as to the hydrophobic component has been withdrawn), Claims 26, 41, 53, 68, 79, and 81-89 are generic to and readable on the elected species. Claim readable on the elected species are 25-35, 37-42, 46, 52-70, 73, 75, and 91-100.

Applicants respectfully request that search and examination continue as to other non-elected plasticized matrix materials and encapsulant species recited in Claims 43, 47, 50, 71, 76, and 90 once the generic claims are found allowable. See MPEP 809.02(c).

II. FORMAL MATTERS

Claims 25, 27-40, 42, 46, 52, 54-67, 69, 70, 73, and 75-76 were rejected under 35 U.S.C. 112, second paragraph, as assertedly being indefinite. This rejection is respectfully traversed.

Applicants respectfully note that the word "substantially" is not indefinite. See MPEP 2173.05(b)(D). A copy of this MPEP section is attached for the Examiner's convenience.

In support of the Examiner's position that the term "substantially" is indefinite, one case from a district court, *E.W. Bliss v. Cold Metal Process Co.*, 174 F. Supp. 99, 122 USPQ 238 (N.D. Ohio 1959) is cited. However, the Examiner's assertion that the term "substantially" may be "as much as 49%" is not in accordance with the particular facts of that case. In *E.W. Bliss*, the district court relied upon the statements in the file history to hold that the claimed limitation "driven substantially by tension on the strip" does not extend to tension supplying 49% of the total power. See *E.W. Bliss*, 174 F. Supp. at 125. In addition, the court noted that the word "substantial" does not connote small or meager. Id. Rather, it includes the "high range of principally or entirely." Id.

In several cases from the Federal Circuit, which has authority over district courts such as the district court in *E.W. Bliss*, the term "substantially" has been held to be definite without any quantitative or numerical definition, so long as one of ordinary skill in the art understands what is claimed. See *York Products, Inc. v. Central Tractor Farm & Family Center*, 99 F.3rd 1568, 1573 (Fed. Cir. 1996); *Pall Corp. v. Micron Seps.*, 66 F.3rd 1211, 1217 (Fed. Cir. 1995); *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819 (Fed. Cir 1988). One of ordinary skill in the art would understand that the term "substantially" as claimed means "principally or entirely." See, for example, page 6, lines 13-17, page 11, lines 13-16, and page 23, lines 20-23. Accordingly, the scope of the pending claims would be reasonably ascertainable to one of ordinary skill in the art when

read in light of the specification. Thus, the requirements of 35 U.S.C. 112 are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

Concerning the term "probiotic", Applicants respectfully note that this term refers to microorganisms that have a beneficial effect on animal and human health. See, for example, the attached reference entitled *Probiotic Additives*, BCCM® News, ed. 2/96.

III. REJECTION UNDER 35 U.S.C. 103(a)

Claims 25, 27-40, 42, 46, 52, 54-67, 69, 70, 73, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,320,669 (Lim et al.) in view of U.S. Patent No. 4,357,358 (Schanze). This rejection is respectfully traversed.

A. LIM ET AL.

Lim et al. discloses a biodegradable thermoplastic composition made of a cereal grain, such as durum wheat, and which may also contain lubricant additives, such as fatty acids or vegetable oils (col. 6, lines 7-26). The cereal grain may be nutritionally reinforced with vitamins or minerals (col. 3, lines 35-39). The edible composition may also contain an edible flavoring agent or an antimicrobial agent (col. 7, lines 5-14). There is no disclosure regarding the amount of vitamins, minerals, flavoring agent, or antimicrobial agent. The molded articles may be in the form of capsules, trays, or bottles. The molded articles may be used for packaging drugs (col. 9, lines 6-14).

The molded compositions of Lim et al. serve to package drugs, for example, in capsules or bottles. Thus, there are two separate entities in Lim et al.: (1) the molded article comprising a cereal grain composition, and (2) a packaged drug. Lim et al. does not teach or suggest an encapsulant dispersed throughout a plasticized mass, wherein the amount of the encapsulant is from about 1% by weight to about 85% by weight, based upon the weight of a matrix material, as recited in Claims 25 and 52 and their dependent claims. Further, Lim et al. does not teach or suggest that the encapsulant and the

plasticized matrix material form an at least substantially homogeneous mixture. Lim et al. also does not teach or suggest the encapsulants recited in Claims 46, 75, and 85-86.

B. SCHANZE

Schanze does not overcome the deficiencies of Lim et al. Schanze discloses animal feedstuffs in the form of pellets (Abstract). The animal feedstuffs contain fibrous agricultural by-product and non-fibrous additives. The animal feedstuffs may also contain lichens (i.e., fungi) (col. 11, line 37; col. 12, lines 56-66). The structured feedstuff of Schanze retains its structural integrity, thereby providing chewability and bite to the feedstuff (col. 6, lines 54-56). The structured feedstuff therefore provides for the proper feeding of cattle and animals.

There is no teaching or suggestion to package the animal feedstuff of Schanze in the cereal grain composition of Lim et al. The beneficial aspect of the feedstuff according to Schanze is the compressed structure containing fibrous material having a specific length (cols. 8-10). There is no teaching, suggestion, or expectation that by placing the lichens in a different composition, such as the cereal grain composition of Lim et al., a feedstuff having the same beneficial effects of chewability and bite would be obtained. Moreover, Lim et al. *teaches away* from incorporating any fungi by disclosing the inclusion of preservatives, such as a fungicide, to prevent growth of fungi. Accordingly, the combination of Lim et al. and Schanze is merely a reconstruction of the claimed encapsulated product through impermissible hindsight.

Even if Lim et al. and Schanze were properly combinable, which they are not, Applicants' claimed encapsulated product would not be obtained. Such a combination would yield a capsule casing that is separate and distinct from any feedstuff pellets or any lichens. The pellets or lichens would not be dispersed throughout the cereal grain capsule of Lim et al. Thus, it would not have been obvious for one of ordinary skill in the art to

make the claimed encapsulated products in view of the combined teachings of Lim et al. and Schanze. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 25 and 52 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 21 and 104 of copending U.S. Serial No. 09/233,443. This rejection is respectfully traversed.

Claims 21 and 104 of copending U.S. Serial No. 09/233,443 do not teach or suggest discrete, solid particles having a substantially uniform shape and a diameter of up to about 10 mm. Nevertheless to avoid any question or obviousness-type double patenting, a Terminal Disclaimer is filed concurrently herewith, thereby rendering the rejection moot. Reconsideration and withdrawal of the rejection are respectfully requested.

V. CONCLUSION

In light of the foregoing remarks, this application is in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

Any shortages in fees should be charged to, or any overpayment in fees should be credited to, Deposit Account No. 501032 (Docket No. BVL-102A).

Respectfully submitted,

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June 17, 2003

Enclosures:
MPEP 2173.05(b)(D)
Probiotic Additives, BCCM® News, ed. 2/96
Terminal Disclaimer
Check for $110.00 (Disclaimer Fee)

CERTIFICATE OF MAILING

I hereby certify that this correspondence dated 6/17/03 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 6/17/03.

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Date: 6/17/03

REFERENCE TO AN OBJECT THAT IS VARIABLE MAY RENDER A CLAIM INDEFINITE

A claim may be rendered indefinite by reference to an object that is variable. For example, the Board has held that a limitation in a claim to a bicycle that recited "said front and rear wheels so spaced as to give a wheelbase that is between 58 percent and 75 percent of the height of the rider that the bicycle was designed for" was indefinite because the relationship of parts was not based on any known standard for sizing a bicycle to a rider, but on a rider of unspecified build. *Ex parte Brummer*, 12 USPQ2d 1653 (Bd. Pat. App. & Inter. 1989). On the other hand, a claim limitation specifying that a certain part of a pediatric wheelchair be "so dimensioned as to be insertable through the space between the doorframe of an automobile and one of the seats" was held to be definite. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986). The court stated that the phrase "so dimensioned" is as accurate as the subject matter permits, noting that the patent law does not require that all possible lengths corresponding to the spaces in hundreds of different automobiles be listed in the patent, let alone that they be listed in the claims.

A. "About"

The term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968). Similarly, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

B. "Essentially"

The phrase "a silicon dioxide source that is essentially free of alkali metal" was held to be definite because the specification contained guidelines and examples that were considered sufficient to enable a person of ordinary skill in the art to draw a line between unavoidable impurities in starting materials and essential ingredients. *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (CCPA 1983). The court further observed that it would be impractical to require applicants to specify a particular number as a cutoff between their invention and the prior art.

C. "Similar"

The term "similar" in the preamble of a claim that was directed to a nozzle "for high-pressure cleaning units or similar apparatus" was held to be indefinite since it was not clear what applicant intended to cover by the recitation "similar" apparatus. *Ex parte Kristensen*, 10 USPQ2d 1701 (Bd. Pat. App. & Inter. 1989).

A claim in a design patent application which read: "The ornamental design for a feed bunk or similar structure as shown and described." was held to be indefinite because it was unclear from the specification what applicant intended to cover by the recitation of "similar structure." *Ex parte Pappas*, 23 USPQ2d 1636 (Bd. Pat. App. & Inter. 1992).

D. "Substantially"

The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation "to substantially increase the efficiency of the compound as a copper extractant" was definite in view of the general guidelines contained in the specification. *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The court held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

BCCM™ News
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PROBIOTICS ADDITIVES

Probiotic Additives: a Healthy Trend?

Probiotic stems from the Greek for 'in favour of life' - the opposite of antibiotic. It was first used to refer to micro-organisms promoting the growth of other micro-organisms(1) or for tissue extracts stimulating the growth of microorganisms. Only later(2, 3) was the term 'probiotic' used in its present sense - referring to micro-organisms that have a beneficial effect on animal and human health.

Probiotics in animal feed are regulated by European Commission Directives.

In general, the probiotic effect is exerted via action in the gastrointestinal tract but beneficial effects have also been reported in the urogenital tract as well.

Bacteria claimed to have probiotic effects are mainly assigned to the lactic acid group and to the genus *Bifidobacterium*. However, numerous reports link beneficial health effects to species of other Gram positives (e.g. *Propionibacterium, Bacillus*), Gram negatives (e.g. *Escherichia coli*), yeasts (e.g. *Candida, Saccharomyces*) and fungi (e.g. *Aspergillus*).

The use of probiotics is most widespread in commercial animal feed products and feed additives. However, probiotic-like yoghurts and other fermented dairy products have been making an impact on the human food market for a number of years. Most of these products claim to have one or more beneficial health effects, such as:

- colonization of the gastrointestinal and/or urogenital tract with potential antagonistic effects on pathogenic bacteria or improved recovery of intestinal disorders;
- beneficial metabolic activities of the probiotic micro-organism (e.g. production of vitamins, or bile salt hydrolase (BSH) activity);
- therapeutic effects (e.g. claimed stimulation of the immune response, and possible protection against early events in carcinogenesis).

Whereas the use of probiotics in animal feeds is regulated by a European Commission Directive (see 'Regulations' below), the present European legislation does not yet cover their use in food products for human consumption. National legislation differs from country to country.

Clearly, the safety of probiotic products manufactured and distributed on a wide scale depends on the correct identification of the micro-organism(s) involved and on the stability of a number of factors directly and indirectly linked to claimed health benefits. The BCCM™/LMG collection's professional identification services offer a number of interesting possibilities for the identification, characterization and safe deposit of probiotic strains (see below).

(1) Lilly and Stillwell, 1965; Science 147, 747-748
(2) Parker, 1974; Anim. Nutr. Health 29, 4-8
(3) Fuller, 1989; J. Appl.Bacteriol. 66, 365-378

Regulations on the Registration of Probiotics as Feed Additives

Guidelines for the identification, characterization and evaluation of probiotic feed additives are set forward in Council Directive 87/153/EEC, modified by the Commission Directives 94/40/EC and 95/11/EC.

One of these guidelines states: "It is necessary to deposit reference material [microbiological strains used in animal feed] in a culture collection that is recognized as an International Depositary Authority (IDA), in accordance with the Budapest Treaty [Budapest, 28 April, 1977; amended 26 September, 1980] in order to have guarantee on the conservation without any change of the microbial strains and consequently of continuity during the industrial use."

Furthermore it is stated that, in all cases, "a copy of the receipt of deposit of the micro-organism with an IDA should be provided, precising the name and the taxonomic description of the micro-organism according to the International Code of Nomenclature".

The BCCM™ consortium has been recognized as an IDA by the World Intellectual Property Organization (WIPO) since 1992. **By depositing bacterial/fungal cultures at one of the relevant BCCM™ collections, all the requirements of the EU Directives are automatically satisfied.** Deposited strains can be analyzed taxonomically and entered in a closed BCCM™ collection as a 'safe deposit', implying that the culture is not published in any BCCM™ catalogue or on-line information network and that subcultures are only made available for the depositor or an authorized mandatary.

Copies of the Commission's directives and amendments are available from the BCCM™ upon request.

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Interview: From the Laboratory to the Consumer

Professor Dellaglio is professor of general and industrial microbiology at the Universita Degli Studi Di Verona in Italy, where his research interests focus on basic and applied research into lactic acid bacteria, propionibacteria and other bacteria related to food. His work brings him into regular contact with the BCCM™/LMG collection in Belgium.

"The collection offers excellent identification and taxonomic facilities," explains Professor Dellaglio. "A member of my research team spent several weeks at BCCM™/LMG working on the genetic identification and characterization of propionibacteria. We have over 80 strains stored there now."

Professor Dellaglio relies on the BCCM™/LMG to provide him with reliable cultures both of the strains deposited there by his research team and others from the collection's extensive catalogue. **"Because the BCCM™/LMG provides information not only on the strain but also on its source and other references I find that I can select a sample with greater confidence," he says. "This translates to repeatable results in the lab - very important to my research."**

The professor is in no doubt that probiotics will prove to be instrumental in protecting against human intestinal disorders through antimicrobial, biochemical and physiological mechanisms. Nevertheless, he is aware that there is currently considerable disagreement on the methodology and efficacy used in the study of probiotic effects. "Opinion ranges from very optimistic to guarded," he says. Professor Dellaglio believes that scientists could improve their credibility in a number of ways, including:

- developing new parameters for strain selection and detection of target bacteria and new technologies for fermentation;
- improving colonization ability through genetic engineering;
- performing both in vitro and in vivo studies followed by clinical trials;
- investigating symbiotic cultures;
- performing collaborative studies between laboratories and dairy/food industries.

Professor Dellaglio advocates the eventual combination of probiotics and prebiotics once the necessary research on symbiotics has been completed. "Since prebiotics stimulate the growth of a host's own beneficial bacteria, I think that they are more easily accepted by consumers," he adds.

The increased use of prebiotics, probiotics and symbiotics should help to reduce the use of antibiotics, which is especially important in the light of growing antimicrobial resistance(1).

But what form will consumer probiotics take? Professor Dellaglio believes that fresh food products - particularly fermented milk products - are the way forward. "But this means that probiotic strains will need to be selected not only for their health-promoting effects but also according to their influence on the texture, aroma and acidity of the product," he points out.

Professor Dellaglio feels that EU legislation for human probiotics is needed, as is the case for animal feed. He believes that genetically modified probiotic micro-organisms may offer even greater benefits but that they must be rigorously tested for safety according to stringent EU protocols.

(1) See BCCM™ News 1

Meeting Report: Probiotics '96

BCCM™/LMG recently contributed to Probiotics '96 meeting entitled "Probiotics in man and animal", organized by the Deutsche Veterinärmedizinische Gesellschaft (DVG), the Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM) and the Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV).

The meeting was held on 20-22 June in the historical Harnack House in Berlin, Germany. We would like to thank Prof. G. Reuter, Prof. J. Krämer, Prof. P. Teufel and Dr. G. Klein for inviting BCCM™/LMG to this interesting symposium which covered:

- general aspects as taxonomy, identification and stability;
- selection of micro-organisms for special applications;
- safe biotechnology with emphasis on the regulatory issues;
- general concepts of probiotics;
- probiotics in the dairy;
- probiotics as pharmaceutical preparations;
- probiotics in animal nutrition.

A round table discussion was held on the 'genetic stability' of Gram positive bacteria, which is becoming increasingly important to a number of issues, including the emergence of antibiotic resistance (1).

BCCM™/LMG made a presentation on "The taxonomy of micro-organisms used as probiotics with special focus on enterococci, lactococci and lactobacilli". The reliability of the identification of lactic acid bacteria by SDS-PAGE of whole-cell proteins was demonstrated by comparison to other traditional, time consuming, genotypic methods. Moreover, the results of a recent comparative study of typing methods were presented: AFLP™, REP-PCR, ERIC-PCR, RAPD analysis and PFGE of rare-cutted restriction fragments revealed different groupings of strains when applied on a selection of Enterococcus faecium strains. An evaluation of the resulting patterns by numerical analysis was shown to be possible; results largely improved by applying more primers and / or restriction enzymes.

Besides the proceedings made available at the conference, **full contributions will be published in one of the next issues of Microecology and Therapy**.

The decision to organize a second Probiotics meeting within two years was accepted with overwhelming enthusiasm. Congratulations for Probiotics '96 and good luck with the organization of Probiotics '98.

(1) See BCCM™ News 1

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BCCM™ Services in the Field of Probiotics

In order to ensure the safe use of probiotics in food, the correct identification of the micro-organism(s) involved is essential. The BCCM™ collections offer identification, characterization and safe deposit services on a routine basis.

Several DNA-fingerprinting techniques (e.g. PFGE of rare-cutted restriction fragments, RAPD, AFLP™) are applied to produce strain-specific fingerprints.

The BCCM™/LMG has investigated more than 3 000 strains belonging to over 200 species of lactic acid bacteria by the one-dimensional SDS-PAGE technique of whole-cell proteins. The resulting database allows fast and reliable identification of the submitted strain to species or subspecies level. Numerical analysis of the protein profiles reveals the relative position of the strain towards a large number of well-known reference strains.

Strains of yeasts submitted to the BCCM™/MUCL are characterized and identified using BCCM™/ALLEV 2.00, an automated yeast identification system that employs both physiological and morphological criteria(1). Its reference database presently includes over 690 taxa and can be updated easily.

(1) See ALLEV 2.00, BCCM™ News 1

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